National Marrow Donor Program®

Entrusted to operate the
C.W. Bill Young
Cell Transplantation Program

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February 10, 2009

Cdr. Elizabeth Montcalm-Smith
Office of Naval Research (ONR 342)
875 N. Randolph St.
Arlington, VA 22203-1995

Subject: **Quarterly Performance/Technical Report of the National Marrow Donor Program®**

Reference: Grant Award #N00014-06-1-1207 between the Office of Naval Research and the National Marrow Donor Program

Dear Cdr. Montcalm-Smith:

Enclosed is subject document which provides the performance activity for each statement of work task item of the above reference for the period of September 1, 2008 to December 31, 2008.

Should you have any questions as to the scientific content of the tasks and the performance activity of this progress report, you may contact our Chief Medical Officer – Dennis L Confer, MD directly at 612-362-3425.

With this submittal of the quarterly progress report, the National Marrow Donor Program has satisfied the reporting requirements of the above reference for quarterly documentation. Other such quarterly documentation has been previously submitted under separate cover.

Please direct any questions pertaining to the cooperative agreement to my attention (612-362-3403 or at cabler@nmdp.org).

Sincerely,

Carla Abler-Erickson

Carla Abler-Erickson, MA
Sr. Contracts Representative

Enclosure: Quarterly Report with SF298

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14. ABSTRACT

1. Contingency Prepardness: Collect information from transplant centers, build awareness of the Transplant Center Contingency Planning Committee and educate the transplant community about the critical importance of establishing a nationwide contingency response plan.

2. Rapid Identification of Matched Donors : Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event.

3. Immunogenetic Studies: Increase understanding of the immunologic factors important in HSC transplantation.

4. Clinical Research in Transplantation**:** Create a platform that facilitates multicenter collaboration and data management.

15. SUBJECT TERMS
Research in HLA Typing, Hematopoietic Stem Cell Transplantation and Clinical Studies to Improve Outcomes

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a. REPORT	b. ABSTRACT	c. THIS PAGE	Same as Report	13	Dennis L. Confer, MD – Chief Medical Office
U	U	U			19b. TELEPONE NUMBER (*Include area code)* 612.362.3425

NATIONAL MARROW DONOR PROGRAM®

Creating Connections. Saving Lives.™

Grant Award N00014-08-1-1207

QUARTERLY
PERFORMANCE / TECHNICAL REPORT
FOR
SEPTEMBER 01, 2008 to DECEMBER 31, 2008

Office of Naval Research

And

The National Marrow Donor Program
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IIA. Contingency Preparedness – Objective 1: Recovery of casualties with significant myelosuppression following radiation or chemical exposure is optimal when care plans are designed and implemented by transplant physicians	
IIA.1.1 Task 1: Secure Interest of Transplant Physicians	**Period 1 Activity:** • During this period we continued planning for a 2009 advanced training course for RITN centers to send staff to. The course is titled Advanced Radiation Medical Emergency training course and conducted in Oakridge, TN at the Radiation Emergency Assistance Center/Training Site (REAC/TS). Class will be held on March 26 & 27, 2009. Course lessons include: o Basic Health Physics & Radiation Protection: Part I o A History of Serious Radiological Incidents: The Real Risk o Health Physics & Contamination Control: Part II o Radiation Detection, Monitoring & Protection Laboratory Exercise & Quiz o Diagnosis & Management of the Acute Radiation Syndrome (ARS) o Diagnosis & Management of Internal Contamination o Diagnosis & Management of Acute Local Radiation Injury & Case Review: Yanango Peru o Radiation Sources & Radiological Terrorism o Radiation Emergency Area Protocol Demonstration o Radiation Emergency Medical Management Drill o Radiation Dose Estimations – Problem Solving Session • During this period we initiated planning for the 2009 RITN conference "Nuclear Terrorism: Hematology/Oncology Center Preparedness" to be held in Bethesda, MD on May 18th (additional details of this conference are listed under AIM II A 2.1).
IIA.1.2 Task 2: GCSF in Radiation Exposure	**Period 1 Activity:** • No activity this period.
IIA.1 3 Task 3: Patient Assessment Guidelines and System	**Period 1 Activity:** • No activity this period.

Enhancements	
IIA 1.4 Task 4: National Data Collection Model	**Period 1 Activity:** • No activity this period.
IIA. Contingency Preparedness – Objective 2: Coordination of the care of casualties who will require hematopoietic support will be essential in a contingency situation.	
IIA.2.1 Task 1: Contingency Response Network	**Period 1 Activity:** • Distributed FY09 RITN participation agreements to all 51 centers and formally invited six (6) additional transplant centers to participate in RITN, all have verbally agreed to participate and their signed participation agreements are under review by their legal teams: o Vanderbilt University in Nashville, TN o CHORI in Oakland, CA o Karmanos Cancer Center in Detroit, MI o Mayo Clinic in Rochester, MN o Mayo Clinic in Phoenix, AZ o City of Hope in Phoenix, AZ • During this period we initiated planning for the 2009 RITN conference "Nuclear Terrorism: Hematology/Oncology Center Preparedness" to be held in Bethesda, MD on May 18, 2009. o We are planning for 200 attendees (a slight increase from the 2007 conference attendance) o This conference will have a group session in the morning to provide a common operating picture then have three (3) interactive breakout workshops held three (3) times in the afternoon so that all attendees have the opportunity to participate. o Morning sessions include: ▪ Threat Scenario Overview ▪ National Disaster Medical System ▪ Medical response expectations 10, 100, 1,000 miles from epicenter ▪ Altered Standards of Medical Care Overview

	▪ NMDP Planning and data collection o Afternoon interactive breakout workgroups include: ▪ Altered Standards of Care ▪ Logistical issues – bed mgmt, use of non-hospital loc, & staffing issues ▪ Provision of medical care – early and late care o The conference will culminate with a report of findings by the afternoon session moderators, with the intent of publishing these findings later in the year.
IIA.2.2 Task 2: Sibling Typing Standard Operating Procedures	**Period 1 Activity:** • No activity this period.
IIA. Contingency Preparedness – Objective 3: NMDP's critical information technology infrastructure must remain operational during contingency situations that directly affect the Coordinating Center.	
IIA.3.1 Task 1: I.S. Disaster Recovery	**Period 1 Activity:** • No activity this period.
IIA.3.2 Task 2: Critical Facility and Staff Related Functions	**Period 1 Activity:** • Business Continuity Planning: o Coordinated the installation of security film on all windows of the NMDP Repository to harden the face of the storage facility in the event of a natural or man made disaster that could compromise the building structure. o Initiated the acquisition of donor center readiness kits to prepare these remote NMDP offices to better respond to incidents that impact their operations locally.

IIB. Rapid Identification of Matched Donors – Objective 1: Increasing the resolution and quality of the HLA testing of volunteers on the registry will speed donor selection.	
IIB.1.1 Task 1: Increase Registry Diversity	**Period 1 Activity:** • No activity this period.
IIB.1.2 Task 2: Evaluate HLA-DRB1 High Res typing	**Period 1 Activity:** • Closed
IIB.1.3 Task 3: Evaluate HLA-C Typing of Donors	**Period 1 Activity:** • Closed
IIB.1.4 Task 4: Evaluate Buccal Swabs	**Period 1 Activity:** • No activity this period.
IIB 1.5 Task 5: Enhancing HLA Data for Selected Donors	**Period 1 Activity:** • No activity this period.
IIB 1.6 Task 6: Maintain a Quality Control Program	**Period 1 Activity:** • No activity this period.
IIB. Rapid Identification of Matched Donors – objective 2: Primary DNA typing data can be used within the registry to improve the quality and resolution of volunteer donor HLA assignments.	
IIB 2.1 Task 1: Collection of Primary Data	**Period 1 Activity:** • No activity this period.

IIB 2.2 Task 2: Validation of Logic of Primary Data	**Period 1 Activity:** • Closed
IIB 2.3 Task 3: Reinterpretation of Primary Data	**Period 1 Activity:** • Closed
IIB 2.4 Task 4: Genotype Lists & Matching Algorithm	**Period 1 Activity:** • No activity this period.
IIB. Rapid Identification of Matched Donors – Objective 3: Registry data on HLA allele and haplotype frequencies and on the nuances of HLA typing can be used to design computer algorithms to predict the best matched donor.	
IIB.3.1 Task 1: Phase I of EM Haplotype Logic	**Period 1 Activity:** • No activity this period.
IIB 3.2 Task 2: Enhancement of EM Algorithm	**Period 1 Activity:** • No activity this period.
IIB 3.3 Task 3: Optimal Registry Size Analysis	**Period 1 Activity:** • No activity this period.
IIB 3.4 Task 4: Target Under-represented Phenotypes	**Period 1 Activity:** • No activity this period.
IIB 3.5 Task 5: Bioinformatics Web Site	**Period 1 Activity:** • Closed
IIB 3.6 Task 6: Consultants to Improve Algorithm	**Period 1 Activity:** • Closed

IIB. Rapid Identification of Matched Donors – Objective 4: Reducing the time and effort required to identify closely matched donors for patients in urgent need of HSC transplants will improve access to transplantation and patient survival in the context of a contingency response and routine patient care.	
IIB.4.1 Task 1: Expand Network Communications	**Period 1 Activity:** • No activity this period.
IIB.4.2 Task 2: Central Contingency Management	**Period 1 Activity:** • No activity this period.
IIB.4.3 Task 3: Benchmarking Analysis	**Period 1 Activity:** • Closed
IIB.4.4 Task 4: Expand Capabilities of Collection and Apheresis Centers	**Period 1 Activity:** • No activity this period.
IIC. Immunogenetic Studies – Objective 1: HLA mismatches may differ in their impact on transplant outcome, therefore, it is important to identify and quantify the influence of specific HLA mismatches. In contingency situations it will not be possible to delay transplant until a perfectly matched donor can be found.	
IIC.1.1 Task 1: Donor Recipient Pair Project	**Period 1 Activity:** • No activity this period.
IIC. Immunogenetic Studies – Objective 2: Even when patient and donor are HLA matched, GVHD occurs so other loci may play a role.	
IIC 2.1 Task 1: Analysis of non-HLA loci	**Period 1 Activity:** • No activity this period.
IIC 2.2 Task 2: Related Pairs Research Repository	**Period 1 Activity:** • No activity this period.

IID. Clinical Research in Transplantation – Objective 1: Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response.	
IID.1.1 Task 1: Observational Research, Clinical Trials and NIH Transplant Center	**Period 1 Activity:** • No activity this period.
IID.1.2 Task 2: Research with NMDP Donors	**Period 1 Activity:** • No activity this period.
IID.1.3 Task 3: Expand Immuno-biology Research	**Period 1 Activity:** • No activity this period.

ACRONYM LIST

AABB	American Association of Blood Banks	IDM	Infectious Disease Markers
AC	Apheresis Center	IHWG	International Histocompatibility Working Group
AHS	American Healthcare Solutions	IND	Investigational New Drug
AML	Acute Myelogenous Leukemia	IS	Information Services
ARS	Acute Radiation Syndrome (also known as Acute Radiation Sickness)	IT	Information Technology
ASBMT	American Society for Blood and Marrow Transplantation	IRB	Institutional Review Board
ASHI	American Society for Histocompatibility and Immunogenetics	KIR	Killer Immunoglobulin-like Receptor
B-LCLs	B-Lymphoblastoid Cell Lines	LN2	Liquid Nitrogen
BMT CTN	Blood and Marrow Transplant - Clinical Trials Network	LSSG	Life Science Strategy Group
BRT	Basic Radiation Training	NCI	National Cancer Institute
C&A	Certification and Accreditation	MHC	Major Histocompatibility Complex
CBMTG	Canadian Blood and Marrow Transplant Group	MICA	MHC Class I-Like Molecule, Chain A
CBB	Cord Blood Bank	MICB	MHC Class I-Like Molecule, Chain B
CBC	Congressional Black Caucus	MUD	Matched Unrelated Donor
CBS	Canadian Blood Service	NCBM	National Conference of Black Mayors
CBU	Cord Blood Unit	NIH	National Institutes of Health
CC	Collection Center	NIMS	National Incident Management System
CFU	Colony Forming Unit	NK	Natural Killer
CHTC	Certified Hematopoietic Transplant Coordinator	NMDP	National Marrow Donor Program
CIBMTR	Center for International Blood & Marrow Transplant Research	NRP	National Response Plan
CLIA	Clinical Laboratory Improvement Amendment	NST	Non-myeloablative Allogeneic Stem Cell Transplantation
CME	Continuing Medical Education	OCR/ICR	Optical Character Recognition/Intelligent Character Recognition
COG	Children’s Oncology Group	OIT	Office of Information Technology

csDSR	Cancer Data Standards Repository	OMB	Office of Management and Budget
CREG	Cross Reactive Groups	ONR	Office of Naval Research
CT	Confirmatory Testing	PBMC	Peripheral Blood Mononuclear Cells
CTA	Clinical Trial Application	PBSC	Peripheral Blood Stem Cell
CWD	Common and Well Documented	PCR	Polymerase Chain Reaction
DC	Donor Center	PSA	Public Service Announcement
DIY	Do it yourself	QC	Quality control
DKMS	Deutsche Knochenmarkspenderdatei	RCC	Renal Cell Carcinoma
DMSO	Dimethylsulphoxide	RCI BMT	Resource for Clinical Investigations in Blood and Marrow Transplantation
DNA	Deoxyribonucleic Acid	REAC/TS	Radiation Emergency Assistance Center/Training Site
DR	Disaster Recovery	RFP	Request for Proposal
D/R	Donor/Recipient	RFQ	Request for Quotation
EBMT	European Group for Blood and Marrow Transplantation	RITN	Radiation Injury Treatment Network
EM	Expectation Maximization	RT	Room Temperature
EMDIS	European Marrow Donor Information System	SBT	Sequence Based Typing
FBI	Federal Bureau of Investigation	SCTOD	Stem Cell Therapeutics Outcome Database
FDA	Food and Drug Administration	SG	Sample Group
Fst	Fixation Index	SSA	Search Strategy Advice
GETS	Government Emergency Telecommunications Service	SSP	Sequence Specific Primers
GCSF	Granulocyte-Colony Stimulating Factor (also known as filgrastim)	SSOP	Sequence Specific Oligonucleotide Probes
GvHD	Graft vs Host Disease	STAR®	Search, Tracking and Registry
HHQ	Health History Questionnaire	TAT	Turn Around Time
HHS	Health and Human Services	TC	Transplant Center
HIPAA	Health Insurance Portability and Accountability Act	TED	Transplant Essential Data
HLA	Human Leukocyte Antigen	TNC	Total Nucleated Cell
HML	Histoimmunogenetics Mark-up Language	TSA	Transportation Security Agency

HR	High Resolution	URD	Unrelated Donor
HRSA	Health Resources and Services Administration	WGA	Whole-Genome Amplified
HSC	Hematopoietic Stem Cell	WMDA	World Marrow Donor Association
IBWC	Immunobiology Working Committee	WU	Work-up
ICRHER	International Consortium for Research on Health Effects of Radiation		